

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/626,943 Confirmation No.: 3231  
Applicant : Rubino  
Filed : July 25, 2003  
TC/A.U. : 1614  
Examiner : G. Polansky  
Customer No. : 38199  
Title : Parenteral Formulations

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**EIGHTH INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicant(s) submit(s) to the Examiner the attached document listing and this paper pursuant to 37 CFR §§1.56 and 1.97-1.98. The:

☒ form(s) and document(s) is/are attached.

This Information Disclosure Statement is submitted:

☒ more than three months from the filing date of this application, but concurrently with a Request for Continued Examination. Therefore, no fees are believed due.

### REMARKS

The following information is provided in accordance with the requirement of 37 CFR §§1.97-1.98. In the event that the Examiner considers the inclusion of this/these item(s) on the attached form(s) inappropriate and strikes out the citation on the form(s), Applicant(s) request(s) that the Examiner indicate consideration of the attached document(s) in the body of the next paper, *i.e.*, Office Action or Notice of Allowability. Because this information disclosure statement (IDS) is in accordance with the provisions of 37 CFR §§1.97-1.98, consideration of this/these document(s) by the Examiner is required (See MPEP §609).

### OFFICE ACTIONS ISSUED BY FOREIGN PATENT OFFICES

In an effort to submit information for consideration by the USPTO, Applicant(s) submit(s) the following:

Application Country/ No.	Date of Office Action or Correspondence	Official Office Action?	English Translation of Office Action?	Correspondence from Agent regarding Office Action*	Response to Office Action Attached
Australia 2003254168	06/02/2008	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	<b>Cited Documents</b> US 5,516,770      EP 0 649 659      US 5,530,006 EP 0 650 730      WO 01/97809      US 5,536,729 US 5,559,121      EP 0 041 795      DE 4,418,115 GB 2,327,611 * all documents were cited in the Information Disclosure Statement filed on November 21, 2003				

Application Country/ No.	Date of Office Action or Correspondence	Official Office Action?	English Translation of Office Action?	Correspondence from Agent regarding Office Action*	Response to Office Action Attached											
Chile 1490-2003	2006	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No											
	2008	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No											
	2009	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No											
	<p align="center"><b>Cited Documents</b></p> <table border="0"> <tr> <td>US 5,516,770</td><td>EP 0 649 659</td><td>US 5,530,006</td></tr> <tr> <td>EP 0 650 730</td><td>WO 01/97809</td><td>US 5,536,729</td></tr> <tr> <td>US 5,559,121</td><td>EP 0 041 795</td><td>DE 4,418,115</td></tr> <tr> <td>GB 2,327,611</td><td></td><td></td></tr> </table> <p>* all documents were cited in the Information Disclosure Statement filed on November 21, 2003</p>					US 5,516,770	EP 0 649 659	US 5,530,006	EP 0 650 730	WO 01/97809	US 5,536,729	US 5,559,121	EP 0 041 795	DE 4,418,115	GB 2,327,611	
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EP 0 650 730	WO 01/97809	US 5,536,729														
US 5,559,121	EP 0 041 795	DE 4,418,115														
GB 2,327,611																
Colombia 05-017.056	08/26/2009	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No											
	02/04/2010	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No											
	<p align="center"><b>Cited Documents</b></p> <table border="0"> <tr> <td>US 5,516,770</td><td>GB 2,327,611</td><td>US 5,530,006</td></tr> <tr> <td>US 5,674,874</td><td>US 6,022,852</td><td>US 6,193,985</td></tr> </table> <p>* US 5,516,770; GB 2,327,611; and US 5,530,006 were cited in the Information Disclosure Statement filed on November 21, 2003</p> <p>* US 5,674,874; 6,022,852; and 6,193,985 are newly cited herein</p>					US 5,516,770	GB 2,327,611	US 5,530,006	US 5,674,874	US 6,022,852	US 6,193,985					
US 5,516,770	GB 2,327,611	US 5,530,006														
US 5,674,874	US 6,022,852	US 6,193,985														

Application Country/ No.	Date of Office Action or Correspondence	Official Office Action?	English Translation of Office Action?	Correspondence from Agent regarding Office Action*	Response to Office Action Attached
Ecuador SP-05-5628	2005	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	<b>Cited Documents</b> Hidalgo, <i>et al</i> , A phase I and pharmacological study of CCI-779, a rapamycin ester cell cycle inhibitor, Abstract No. 606O, Annals of Oncology, 11(4):133, October 2000 US 5,516,770                      EP 0 649 659                      US 5,530,006 EP 0 650 730                      WO 01/97809                      US 5,536,729 US 5,559,121                      EP 0 041 795                      DE 4,418,115 GB 2,327,611 * all documents were cited in the Information Disclosure Statements filed on November 21, 2003 and February 26, 2007				
Russian Federation 2005105301	05/23/2007	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	10/30/2007	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	<b>Cited Documents</b> WO 01/97809                      US 5,516,770                      US 5,530,006 GB 2,327,611 * all documents were cited in the Information Disclosure Statement filed on November 21, 2003				
Vietnam 1-2005-00241	01/11/2007	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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Application Country/ No.	Date of Office Action or Correspondence	Official Office Action?	English Translation of Office Action?	Correspondence from Agent regarding Office Action*	Response to Office Action Attached
Europe 03771828.5	06/30/2009*	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	09/17/2010 Summons to Attend Oral Proceedings	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
		(a) Teva's Response dated 11/23/2010 to the Summons to Attend Oral Proceedings <b>Cited Documents</b> (i) "Modern Pharmaceutics", 4 <sup>th</sup> Ed., Banker & Rhodes, Eds., Marcel Dekker Inc.: New York, NY, July 4, 2002, pages 388-393 (ii) "Pharmaceutical Dosage forms and Drug Delivery Systems", 7 <sup>th</sup> Ed., Ansel et al., Eds., Lippincott Williams and Wilkins: Philadelphia, PA, 1999, pages 405-406 (iii) "Handbook of Pharmaceutical Excipients", 3 <sup>rd</sup> Ed., Kibbe, Ed., American Pharmaceutical Association: Washington, DC, 2000, pages 49-52 and 140-141			
		(b) English translation of Wichmann's Response dated 11/24/2010 to the Summons to Attend Oral Proceedings and English translation thereof <b>Cited Documents</b> WO 99/56727                      WO 97/22358 "Römp Lexikon Chemie", 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, pages 229, 423, 759-760, and 3472-4573			
		(c) Applicant's Response dated 12/03/2010 Summons to Attend Oral Proceedings			
	03/01/2011 Revocation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	03/01/2011 Minutes of Oral Proceedings	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

\* confidential information redacted from correspondence.

♦ This is the date Applicant's Response to the Notice of Opposition dated December 22, 2008

Pursuant to 37 CFR §1.98(a)(1), this/these item(s) is/are included on the attached form entitled "Other information submitted for consideration by the Office". The attached are/is submitted solely in an effort to ensure that the Examiner has an opportunity to consider information that was considered by a foreign patent office(s). However, Applicant(s) maintain(s) that the mere submission of this/these document(s) is not an admission that the same is material to patentability (See MPEP §609). Also provided is/are the official Response(s) thereto, where applicable.

#### DOCUMENTS IN A FOREIGN LANGUAGE

Document(s) **24, 26, 28, and 30** is/was published in a foreign language and machine English translation(s) are provided as documents **25, 27, 29, and 31**. However, the following brief comments are provided for these documents:

- Document **24**: This document provides a standard definition for an oxidation inhibitor.
- Document **26**: This document provides a standard definition for butylated hydroxyanisole (BHA).
- Document **28**: This document provides a standard definition for citric acid.
- Document **30**: This document provides a standard definition for tocopherol.

#### MONTHS OF PUBLICATION

The month(s) of publication for document(s) **24-36** could not be determined. The year/years of publication document(s) **24-31** is after the effective US filing date and/or

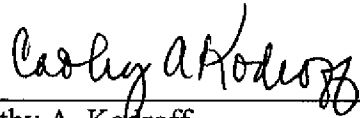
US Patent Application No. 10/626,943  
Our Ref: AM100802  
Eighth Information Disclosure Statement  
Page 7

the foreign priority date of the present application so that the particular month of publication of the document(s) is not in issue (MPEP §609).

The Examiner is respectfully requested to consider the document(s) identified in this paper and in the attached form(s) during the course of examination of this application.

Respectfully submitted,

HOWSON & HOWSON LLP

A handwritten signature in cursive script, appearing to read "Cathy A. Kodroff", written over a horizontal line.

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